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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,285	09/26/2001	Sven Enerback	13425-042001 / 00298-US	9639
26161	7590	04/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/963,285

Applicant(s)

ENERBACK ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 10-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/22/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-9 and 35 in the paper filed 3/5/04 is acknowledged.

Claims 10-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response filed 3/5/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 4, 5, 7, 8, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Pitha-Rowe et al. (WO 01/18039).

Pitha-Rowe et al. disclose an isolated promoter region comprising a nucleotide sequence consisting nucleotides 1692 to 1703 of SEQ ID NO:1 (See Fig. 2 C, A1 (4PM), nucleotides 12-23), operably linked to the SAP reporter gene (encoding alkaline phosphatase), carried on a reporter plasmid, and transfected into a cell (see page 16, line 23 page 18, line 7).

Claims 1 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Cochran et al. (US Patent 6,221,361) or Breton et al. (US Patent 6,562,958).

Cochran et al. disclose a region comprising a nucleotide sequence consisting of nucleotides 1692 to 1703 of SEQ ID NO: 1 which would, in the absence of evidence to the contrary, possess FOXC2 promoter activity (see SEQ ID NO: 84 of Cochran et al., sequence alignment attached; see SEQ ID NO: 713 of Breton et al., alignment shown in attachment).

Claims 1-6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Miura et al. (Genomics 41:489-492 (1997)).

Miura et al. disclose a promoter region comprising a nucleotide sequence consisting of nucleotides 1692-1703, 1250-1749, and 1250-2235 of SEQ ID NO :1 (see attached sequence alignment). The region is contained within a recombinant construct (see page 490, first column, lines 1-10). The promoter region is operably linked to the FOXC2 encoding nucleotide sequence (see page 490, first column). The construct is contained in a vector, transformed in a host cell (the human genomic EMBL3 library, page 490, first column). It is noted that the language "comprising" is open and thus the claim encompasses nucleotide regions including nucleotides other than the recited nucleotides.

Claim 35 is rejected under 35 U.S.C. 102(e) as being anticipated by Breton et al. (US Patent 6,562,958), Mezes et al. (US Patent 5,993,813); or Wang (US Pat. Appl. Pub. US 2003/0204075 A9).

The claim recites a nucleic acid comprising a nucleotide sequence selected from the group consisting of certain specified nucleotides from SEQ ID NO:1, operably linked to a heterologous coding sequence. The specification defines "heterologous coding sequence" as any coding sequence other than one that encodes a naturally occurring FOXC2 protein (page 9, line 30). Breton et al. disclose a nucleic acid comprising a nucleotide sequence which is 1692-1703 of SEQ ID NO: 1, operably linked to a heterologous coding sequence (see SEQ ID NO: 713, alignment shown in attachment); Mezes et al. disclose a nucleic acid comprising a nucleotide sequence which is nucleotides 223-231 of SEQ ID NO: 1 operably linked to a heterologous coding

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sequence (see SEQ ID NO: 35, alignment shown in attachment); Wang disclose a nucleic acid comprising a nucleotide sequence which is nucleotides 359-375 of SEQ ID NO:1 operably linked to a heterologous coding sequence (see SEQ ID No. 9718, alignment shown in attachment).


Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


REMY YUCEL, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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